Decision Tree for Inclusion of Women in Clinical Research
(not an NIH-Defined Phase III Clinical Trial)

Human Subjects involved (even if exempted under 45 CFR 46)?

YES — *Inclusion policy applies despite exemption*

NO → *Inclusion policy does not apply*

Is a NIH-Defined Phase III Clinical Trial proposed?

YES → **GO TO: Decision Tree for Inclusion of Women in NIH-Defined Phase III Clinical Trials**

NO

Is gender representation acceptable?

1. Both genders are included in scientifically appropriate numbers? ***(Code G1)*** **or**
2. One gender is excluded because one of the following applies ***(Code G2: females only, G3: males only)***
   - Inclusion is inappropriate with respect to their health
   - Research question is relevant to only one gender
   - Prior evidence strongly suggests no gender difference
   - Data exists for excluded gender; duplicative studies are unnecessary; **or**
3. One gender excluded or limited because subject selection is constrained due to purpose of research? ***(Code G2: females only, G3: males only)*** **or**
4. Gender representation of specimens or datasets cannot be accurately determined **and** this does not compromise the scientific objectives? ***(Code G4: gender representation unknown)***

YES

ACCEPTABLE
G1A, G2A, G3A, or G4A

Describe: inclusion plan, any gender exclusions, plans for analysis and outreach. State why this is scientifically acceptable.

ABSENT
No Information

UNACCEPTABLE

Contact

Scientific Review Administrator

NO

UNACCEPTABLE
G1U, G2U, G3U, or G4U

Negative impact on score. Describe: inclusion plan, any gender exclusions, plans for analysis and outreach. State why this is scientifically unacceptable.